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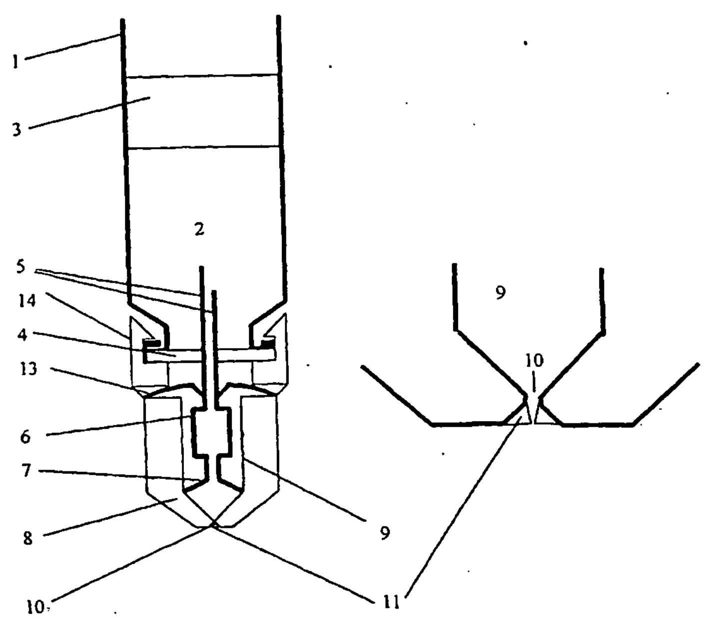

(57) Abstract: A jet injector is described which clips to the front of a standard drug ampoule and is energised by pressing the assembly against the skin of the patient. The pressure deforms a biaxially curved spring which buckles reversibly to impact the drug delivery tube, causing a high pressure transient. This generates a high speed droplet which cuts a track in the skin. The drug may then be administered with a syringe in the normal manner. An elastomeric non return valve may be incorporated.

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DISPOSABLE JET INJECTOR

Jet injectors have been in use for a long time. In the main, they require a significant amount of drive energy and deliver the dose so rapidly that it causes subcutaneous damage.

According to the present invention there is jet injector which is energised by pressing the device against the skin of the patient. The pressure deforms a biaxially curved spring which may relax by reversibly buckling. The fast moving relaxing spring may impact on a crimp in a drug delivery tube to generate a high pressure at the nozzle end. The nozzle end of the drug delivery tube may be flared to form a small piston within a cylinder comprising the exit nozzle. The exit nozzle may be in the form of a slit or non circular cross section. There may be an elastomeric non return valve to prevent ingress of infection or air. The device may clip onto the ampoule in such a manner that removal will cause such damage that the system becomes inoperable. A point contact of the nozzle on the skin may provide not only a good hydraulic seal but also generate a radially decreasing stress distribution within the soft tissue which will ensure that the drug is delivered to the full depth of the track. The biaxially curved spring may be so formed as to provide a high mechanical advantage leverage system to reduce the forces applied to the skin of the patient.

Jet injectors have been in use for over half a century. A high velocity droplet of fluid may pierce the skin and cut a track through the soft subcutaneous tissue. A problem of the earlier injectors was that a jet of fluid fast enough to cut the toughest of skins would also penetrate too deeply, especially for drugs like insulin that must be deposited in the subcutaneous fat layer. By using a single droplet, viscous forces attenuate it rapidly, so providing aggressive cutting at the dermis but ensuring controllable range. This effect may be enhanced by use of a planar jet from a slit like nozzle.

Most jet injectors use a significant power source. Compressed gas is a favourite, though springs and even explosive charges have been used. In the present device, a spring is used, though the cutting drop is of such a small volume that just pressing the device against the skin is sufficient to cock and fire the device.

There is a biaxially curved spring. This is compressed by applying a couple at the edge. The stress in the spring increases until is almost planar at which point it buckles reversibly and turns inside out. The centre of the spring is travelling very fast at the minimum energy configuration. If there is a hole through the centre of the spring such that it may travel along the drug delivery tube, it may be arranged that the centre of the spring may impact on a crimp in the drug delivery tube creating a very high transient load. This load will be transmitted to the end of the drug delivery tube where it may actuate a micro piston to eject a fast droplet of drug.

The main dose may be delivered manually from the ampoule in the usual manner, by depressing the piston. This may be done very slowly to minimise soft tissue damage. A silicone non return valve may be fitted at the nozzle. This will inhibit back flow of material that might cause cross infection. It will also inhibit inflow of air due to thermal contraction of the fluid in the ampoule. Air in the delivery tube would inhibit the pump operation.

An embodiment is shown in section in figure 1, with an enlarged view of the nozzle and valve for clarity. There is an ampoule, 1, with liquid drug, 2, rubber piston, 3, and rubber septum, 4, disposed in the usual configuration. There is a drug delivery tube, 5, which pierces the septum, 4. This has a crimp, 6, midway along its length and a flare, 7 at the outlet end. There is a injection moulded end cap, 8, which comprises; a cylinder, 9, and nozzle, 10. There is also an elastomeric non return valve, 11, on the outer surface, 12. There is a biaxially curved stainless steel spring, 13, and an injection moulded holder, 14. The holder clips onto the ampoule as the drug delivery tube pierces the ampoule. The holder, 14, and end cap, 8, may clip together or be the same moulding with a bayonet fitting to accept a somewhat rectangular shaped spring together with a flexible connection to permit compression of the spring.

In operation, the ampoule piston is advanced with the system held vertically to expel any air. The end cap is then pressed against the skin of the patient which in turn flattens the biaxially curved spring. This then pops through the maximum strain configuration and accelerates toward impact with the drug delivery tube. The impact is conducted along the tube to the flared end and the drug in the cylinder, 9, is subject to a very high pressure. This high pressure ejects a droplet of drug through the

nozzle, the elastomeric non return valve and the skin of the patient. A pressure wave will also propagate up the delivery tube into the ampoule. The constriction associated with the crimp will attenuate this. The change in internal diameters of the crimp and ampoule will ensure that the pressures transmitted to the ampoule will be very small indeed.

There will be a click indicating that the spring has fired and produced a track. The piston in the ampoule may then be depressed to deliver the drug. In the unlikely event of an unsuccessful pierce, it will be impossible to depress the plunger, the hydraulic seal of the nozzle to the skin being good to several atmospheres. Should the pressure be inadvertently removed, the spring will click back to its original position indicating that the injection is over. The balance of the injection may be repeated at a new site.

The biaxially curved spring may be any desired shape. It may also be cut or formed in such a fashion that the end cap may exert a small force over a large distance to complete compression, so reducing the loading on the skin of the patient. The zone around the hole may be formed in a conical shape to more effectively spread the load on impact. If the spring has a rectangular planform, it may be fitted to an integral holder, 14, and end cap, 8, assembly by insertion and rotation by 90°. In addition, the raising of the angled tips about the pressure point of the holder will provide a significant amount of travel, so reducing the load at the injector skin interface required to cock the device.

The holder 14 may have a number of radially disposed clips, as shown, engineered so that clipping to the ampoule takes the root of the cantilever clip close to its failure strain. It will be difficult to splay a number of such clips simultaneously to remove the injector. Any effort to splay them is likely to exceed the strength of the carefully engineered cantilevers, causing them to snap off. In this manner, the injector cannot be re-used. This will reduce the risk of infection and will also prevent use with a rival manufacturers ampoules.

CLAIMS

1. A jet injector which is energised by pressing the device against the skin of the patient.

2. A jet injector powered by a biaxially curved spring which compressed by flattening with a couple at the periphery and in which the compression energy is converted into kinetic energy by reversibly buckling past the flattened configuration.

3. A jet injector according to the claims 1 and 2 in which the fast moving biaxially curved spring may impact on a crimp in a drug delivery tube to generate a transient high pressure.

4. A jet injector according to claims 1 to 3, in which the nozzle end of the drug delivery tube may be flared to form a small piston within a cylinder which comprises the exit nozzle.

5. A jet injector in which the exit nozzle may be in the form of a slit or non circular cross section.

6. A jet injector according to the claims 1 to 5 which incorporates an elastomeric non return valve to prevent ingress of infection or air.

7. A jet injector according to claims 1 to 6, which may clip onto an ampoule in such a manner that removal will cause such damage that the system becomes inoperable.

8. A jet injector that exerts a point contact of the nozzle on the skin to provide both a good hydraulic seal and also a radially decreasing stress distribution within the underlying soft tissue which will ensure that the drug is delivered to the full depth of the track.

9. A jet injector that comprises a biaxially curved spring formed to provide a high mechanical advantage leverage system which permits cocking with a small force operating through a large distance.

Figure 1